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(54) Title: ADJUSTABLE ORTHOTICS

(57) Abstract

An orthotic assembly comprising a main foot-supporting body and an orthotically functional and interchangeable component. The interchangeable component is releasably positioned and retained by the main body. A set of different interchangeable components having various configurations and densities affords a range of foot accommodations. A tooling schema is also provided for the making of the orthotic assembly according to the invention.

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DESCRIPTION

ADJUSTABLE ORTHOTICS

Field of Invention

This invention relates both to orthotic devices designed for use within articles of footwear (e.g., shoes) and for removable insoles for such articles, such items hereinafter collectively termed "Orthotics" in the plural or "Orthotic" in the singular. "Orthotic Assembly" denotes a particular type of Orthotic comprising a plurality of distinct components. An "article of footwear" includes shoes, boots, sandals, and the like.

Background

While the beneficial value of Orthotics is widely accepted today, medical professionals have found that the design and fabrication of Orthotics frequently involve some compromise. Specific issues to be considered include the manufacturing process, the style and length of the Orthotic, the materials used, and various physical attributes of the Orthotic, including, without limitation, dimensions, weight, degree of rigidity, and amount of cushion.

Orthotics are manufactured by several methods, including the following: (1) heating and molding (often by vacuum-forming) of one or more laminar sheets of thermoformable

material (such process generally being termed "thermoforming"), often followed by secondary operations including machine grinding, such grinding typically being done on the underside and perimeter of the Orthotic; (2) automated machine milling of a molded blank; and (3) molding of a thermoplastic or thermoset material within a mold which encapsulates and fully defines the part as it is molded. Frequently, a final step in all methods is the application of a cover material to the Orthotic's top surface. Thermoforming, the most common approach today, has evolved to utilize a large and diverse range of materials, often in quite advantageous multi-layer combinations.

Orthotics are typically designed and constructed as either "3/4-length" or "full-length." The full-length unit extends in length to lie beneath the entire plantar surface of the foot (i.e., from the back of the heel to the tip of the toes). The ¾-length unit, by contrast, extends from the back of the heel to an area under the ball of the foot. If the article of footwear allows sufficient room, and if the Orthotic is sufficiently flexible at the ball of the foot, a full-length Orthotic is usually preferred. If, however, there is insufficient space in the article of footwear, or if the Orthotic is relatively rigid, a ¾-length Orthotic is generally preferred. Two common problems inherent in a ¾-length Orthotic, however, are the abrupt discontinuity in rigidity at the termination of the Orthotic under the ball of the foot and the tendency of the Orthotic to

slide relative to the article of footwear under certain conditions.

The Orthotics industry employs a wide variety of materials, ranging from very soft to extremely rigid. A particular challenge arises in cases where substantial structural rigidity is desired in combination with substantial cushion. A laminar design providing at least a structural layer and a cushion layer can be an effective approach, but often at the expense of greater stack height and weight. Any increase in the stack height or weight of an Orthotic is generally undesirable, and in some cases can render the Orthotic unacceptable to the consumer or for a particular application.

Another approach is to simply select a material, or combination of materials, which offers a compromise between rigidity and cushion. This approach can also be problematic, however, raising a number of questions: Is the Orthotic sufficiently rigid? Does the Orthotic provide sufficient cushion? If the Orthotic style is full-length, does it allow the desirable flexibility at the ball of the foot while maintaining adequate structural support in the midfoot and rearfoot? And, if the Orthotic is ¾-length, does it present either of the "abrupt transition" or "slide" problems mentioned above?

Orthotics are typically either custom-made (to fit a particular set of feet), or generic (to fit an "average" set of feet) for mass merchandising. Custom-made

Orthotics are typically much more expensive than generic Orthotics. In order to appeal to the largest population, generic Orthotics are designed with a very low height in the area of longitudinal-arch support. For this reason, generic Orthotics often provide ineffective or insufficient support for the longitudinal arch in the case of consumers having moderate to high longitudinal arches. A further shortcoming of both generic and custom-made Orthotics is a general lack of adjustability. Greater adjustability in Orthotics would be desirable for many reasons, including the following: (1) Often the user of Orthotics must undergo an acclimatization process which could be greatly facilitated with greater adjustability, (2) Generally the optimal design of an Orthotic will vary depending upon the particular activity of the wearer (e.g., standing vs. walking vs. running), (3) Frequently a patient receiving custom Orthotics must have such Orthotics fabricated or modified several times with iterative changes before the desired fit is achieved, and (4) In many cases the consumer will spend considerable money for a set of Orthotics which immediately prove to be worthless simply because a certain non-adjustable aspect of the Orthotic is, upon use of the Orthotic, deemed to be intolerable by the wearer.

Summary and Objects

It is the object of the invention to provide an Orthotic which affords solutions to the aforementioned

shortcomings of currently available Orthotics. The invention applies to generic and custom-made Orthotics, as well as to full-length Orthotics and those which are less than full length, e.g., ¾-length. Of course, other less than-full-length Orthotics, such as those for positioning under only a portion of the foot, e.g., the heel, arch, or ball of the foot, are also within the scope of this invention. Specific objects of the invention include the following:

1. Provision of convenient adjustability of an Orthotic in the region of longitudinal-arch support by means of an interchangeable component, such adjustability encompassing both material density and the dimensional shape of the Orthotic in such region.
2. In an Orthotic with such an adjustable longitudinal-arch support, to provide the ability for the user to "fine tune" the fit, function, or comfort of the Orthotic by making such adjustments iteratively until achievement of the desired result.
3. To provide an Orthotic wherein the use of an interchangeable component can impart to the Orthotic an adjustable density in a specific area thereof, with such density being the same or different from that of other regions of the Orthotic.
4. To provide an Orthotic which, having a density differential by region, thereby affords a

solution to the "abrupt discontinuity" problem discussed above.

5. To provide an Orthotic which allows the user to gradually modify the density and/or height of an interchangeable component for the purpose of facilitating a process of controlled acclimatization or progressive correction.

6. To provide an Orthotic which allows the user to readily and reversibly modify a region of the Orthotic, e.g., the longitudinal-arch support, heel region, toe region, and/or ball-of-the-foot region, to better suit the user's needs as these vary according to specific activities of the user.

7. To provide an adjustable Orthotic wherein the user, by selecting an appropriate style of an interchangeable component, can specifically include (or exclude) a protuberance of variable height in the region just proximal to the area of the metatarsal heads, thereby gaining the added benefit of a device commonly called a "metatarsal pad."

8. To provide an Orthotic which allows the user to periodically replace an interchangeable component after the same has deteriorated in some respect from its original condition.

9. To provide interchangeable components in various colors conforming to a color-coded system designating variations in physical properties.

10. In a preferred embodiment, to provide a cushion layer over a structural layer in at least a portion of the region of the longitudinal-arch support.

11. To provide an economical tooling design for producing Orthotics.

12. To provide an article of footwear comprising an orthotic assembly functionally associated therewith, either during the original construction of the article or thereafter, such as by insertion of an after-market purchased orthotic assembly. As used herein, "article of footwear" refers to any device worn on the foot, and includes, without limitation, shoes, boots, and sandals. Representative examples of shoes include athletic shoes (e.g., running, track, tennis, and basketball shoes) and men's and women's dress shoes. Representative examples of boots include work boots, ski boots, an hiking boots. Other non-limiting examples of articles of footwear include roller skates (including in-line skates), dance shoes, and ice skates.

One aspect of the invention concerns an Orthotic Assembly which comprises a main body and one or more interchangeable components. Another aspect of the invention relates to a modular tooling design for more economical production of Orthotics.

The invention will be better understood, and further features, objects, and advantages thereof will become more apparent from the ensuing detailed description taken in conjunction with the drawings.

Brief Description of the Drawings

FIG. 1 is a schematic cross section illustrating a portion of an Orthotic with an interchangeable component to be installed into the main body from the bottom.

FIG. 2 is a schematic cross section illustrating a portion of an Orthotic with an interchangeable component to be installed into the main body from the top.

FIG. 3 is a schematic cross section illustrating a portion of an Orthotic with three interchangeable components, each to be installed into the main body from the top.

FIG. 4 is a schematic perspective illustrating an Orthotic with an interchangeable component to be installed into the main body from the side.

FIG. 5 is a schematic perspective illustrating an Orthotic with an interchangeable component to be installed into the main body from the bottom.

FIG. 6 is a schematic perspective illustrating an Orthotic with an interchangeable component to be installed into the main body from the top.

FIG. 7 is a schematic perspective illustrating an Orthotic with an interchangeable component to be installed into the main body from the side, such interchangeable component having a protuberance in the region just proximal to the area of the metatarsal heads.

FIG. 8 is a schematic perspective illustrating tooling utilized in one possible manufacturing process for producing an Orthotic of the current invention.

FIG. 9 is a schematic perspective illustrating the molded product after removal from the mold.

FIG. 10 is a schematic perspective illustrating a set of tooling employing a modular design.

FIG. 11 is a schematic perspective of a set of interchangeable components varying in density.

FIG. 12 is a schematic perspective of a set of interchangeable components varying in configuration.

FIG. 13 is a schematic perspective of a set of interchangeable components varying in both density and configuration.

FIGS. 14A-C are schematic perspectives of an Orthotic which receives a complementary interchangeable component and which has a cover.

FIGS. 15A-C are schematic perspectives of an Orthotic with a cover which is selectively attached to form a pocket which accommodates an interchangeable component.

FIGS. 16A-B are schematic perspectives of an Orthotic with expansion slits to facilitate the accommodation of an interchangeable component.

FIGS. 17A-B are schematic perspectives of an Orthotic with expansion slits to facilitate the accommodation of an interchangeable component and with a cover.

FIG. 18 is a schematic perspective of the underside of an Orthotic, which underside incorporates a grid pattern of material voids.

Detailed Description

Referring to FIG. 1, one possible embodiment of the invention is depicted showing a portion of an Orthotic Assembly comprising a main body 10 ("Main Body") and an interchangeable component 12 ("Interchangeable Component") in the general area of the longitudinal arch. The Main Body 10 has an accessible vacuity 15 (the "Vacuity") on the underside for releasably receiving the Interchangeable Component 12. Both the Main Body 10 and the Interchangeable Component 12 are constructed of materials suitable for a foot support device. The Vacuity 15 is defined by a material which is sufficiently flexible and stretchable to allow the releasable introduction of the Interchangeable Component 12. The Interchangeable

Component 12 fits within such Vacuity 15 on the underside of the Main Body 10, preferably with a precise mating fit at the interface of the Interchangeable Component 12 with the Main Body 10. A lip 14 at the perimeter of the Vacuity 15 has a mating configuration to a beveled edge 16 of the Interchangeable Component 12, ensuring retention of the Interchangeable Component 12 within the Main Body 10.

In preferred embodiments, the Interchangeable Component 12 has a substantially homogeneous and uninterrupted surface, lacking any distinct fastening members, and does not require use of an adhesive or Velcro-like substance to maintain its installed position in the Main Body 10. The Interchangeable Component 12, when installed in the Main Body 10, is most preferably definitively located and adequately retained by the sole and sufficient means of an accommodating Vacuity 15 in the Main Body 10, which Vacuity 15 is shaped to accomplish a mating fit with the Interchangeable Component 12.

FIG. 2 depicts another embodiment of the invention. Here the Interchangeable Component 12 is positioned in the area of the longitudinal arch, but in this case the Interchangeable Component 12 is designed to be installed from the top side of the Main Body 10. The Interchangeable Component 12 enjoys a conforming fit with respect to an accessible Vacuity 15 within the Main Body 10. Both the Main Body 10 and the Interchangeable Component 12 are preferably constructed of materials suitable for a foot support device. The Vacuity 15 is preferably defined by a material which is sufficiently

flexible and stretchable to allow the releasable introduction of the Interchangeable Component **12**. A rim **18** at the perimeter of the Vacuity **15** has a mating configuration to a recessed perimeter **19** of the Interchangeable Component **12**, ensuring retention of the Interchangeable Component **12** within the Main Body **10**.

As in the embodiment shown in Figure 1, the Interchangeable Component **12** has a shape configured for functional support of the longitudinal arch. Furthermore, such Interchangeable Component **12** has a substantially uninterrupted surface, preferably lacking any distinct fastening members and not requiring the use of any adhesive or Velcro-like substance to maintain its installed position. The Interchangeable Component **12**, when installed in the Main Body **10**, is both definitively located and adequately retained by the sole and sufficient means of an accommodating, accessible Vacuity **15** in the Main Body **10**, which Vacuity **15** is precisely shaped to accomplish a mating fit with the shape of the Interchangeable Component **12**.

FIG. 3 shows another embodiment of the invention. In this case there are multiple Interchangeable Components **12A**, **12B**, and **12C** corresponding to Vacuities **15A**, **15B**, and **15C**. The profiles depicted represent a preferred embodiment of the invention. Each combination of Interchangeable Component **12** and Vacuity **15** constitutes a matching set, and these sets are positioned according to their orthotic function in the areas of the heel, the arch, and the ball of the foot, respectively. As shown, each Interchangeable

Component 12 is depicted as being installed from the top side of the Main Body 10, but one or more of each of Interchangeable Components 12A, 12B, or 12C could alternatively be installed from the side or bottom of the Main Body 10. Of course, in such embodiments corresponding reconfigurations of the Main Body 10 would be employed. Preferably, each Interchangeable Component 12 enjoys a conforming fit with respect to the corresponding Vacuity 15 within the Main Body 10. As before, both the Main Body 10 and each Interchangeable Component 12 are preferably constructed of materials suitable for a foot support device, except that each Vacuity 15 is preferably defined by a material which is sufficiently flexible and stretchable to allow the releasable introduction of the corresponding Interchangeable Component 12. As before, a rim 18 comprising at least a portion of the perimeter of Vacuity 15B has a mating configuration to a recessed perimeter 19 of Interchangeable Component 12B, providing for retention of the Interchangeable Component 12B within the Main Body 10. Likewise, lips 14 at the perimeter of each of Vacuities 15A and 15C have mating configurations to a beveled edges 16 characteristic of each of the Interchangeable Components 12A and 12C, such mating configuration enabling retention of the Interchangeable Components 12A and 12C within the Main Body 10.

As in the embodiments shown in FIGS. 1 and 2, each of Interchangeable Components 12A, 12B, and 12C has a shape suitable for its orthotic function, which shape is substantially standard and customary for its orthotic function. Furthermore, each of such Interchangeable

Components **12A**, **12B**, **12C** has a substantially homogeneous and uninterrupted surface, lacking any distinct fastening members (i.e., each is "fastener free") and not requiring the use of any adhesive or Velcro-like substance to maintain its installed position. Each of the Interchangeable Components **12A**, **12B**, and **12C**, when installed in the Main Body **10**, is both definitively located and adequately retained by the sole and sufficient means of matching and accommodating Vacuities **15A**, **15B**, and **15C**, these being shaped to accomplish a substantially mating fit with Interchangeable Components **12A**, **12B**, and **12C**, respectively.

FIGS. 4-6 show preferred embodiments of the invention comprising an Orthotic Assembly having a **Main Body 10** and an Interchangeable Component **12**, which Interchangeable Component **12** fits into a mating Vacuity (not illustrated but designated in its approximate location by number **25**) within the Main Body **10** via a slot **24** (hereinafter termed the "Entry Port"). In these embodiments the mating Vacuity substantially encapsulates the Interchangeable Component **12**, such type of Vacuity hereinafter termed a "Conforming Enclosure." While FIGS. 4, 5, and 6 illustrate different Entry Port **24** locations, there is a male-to-female fit evident upon insertion of the Interchangeable Component **12** into the Conforming Enclosure **25** within the Main Body **10**, which fit serves to both establish and secure the relative locations of the Interchangeable Component **12** and the Main Body **10** of the Orthotic Assembly. As with the other embodiments of the invention, the Interchangeable Component **12** has a

substantially homogeneous and uninterrupted surface, lacking any distinct fastening members, and preferably does not require the use of any adhesive or Velcro-like substance to maintain its installed position. Both the Main Body **10** and the Interchangeable Component **12** are preferably constructed of materials suitable for a foot support device, but the Conforming Enclosure **25** is defined by a material which is sufficiently flexible and stretchable to allow the releasable introduction of the Interchangeable Component **12** and to allow the introduction of an Interchangeable Component **12** having a different size in at least one dimension (e.g., in height) than that of the Conforming Enclosure **25**.

Designing an Orthotic Assembly to have an Interchangeable Component **12** as illustrated in the Figures allows for an easy and convenient means of "fine tuning" a particular portion, e.g., the longitudinal-arch-support region, heel region, and/or ball-of-the-foot region, of an Orthotic through an iterative process involving the trial of various different versions of the Interchangeable Component **12**. These various versions of the Interchangeable Component **12** can vary in both physical dimensions (e.g., height) and material density, and the Interchangeable Component **12** can be color-coded to designate such variations. Quite obviously, the selection of a version of the Interchangeable Component **12** having a different material density from that of the Main Body **10** will produce an Orthotic device with differential density by region (e.g., more stiffness at the area of longitudinal-arch support and less stiffness at the area

of the ball of the foot). This capacity for differential density by region affords an important benefit in allowing a solution to the "abrupt discontinuity" problem discussed above. Another unique and significant benefit of the invention is that it allows the user to gradually modify the density and/or dimension(s) (e.g., height) of the Interchangeable Component **12** over time for the purpose of facilitating a process of acclimatization or for the purpose of accomplishing progressive correction. Yet another unique and significant benefit of the invention can be seen in the ability afforded the user to readily and reversibly modify one or more regions of the Orthodic, e.g., the region of longitudinal-arch support, to better suit specific activities (e.g., walking versus playing basketball). Another benefit of the invention can be seen in the ability to periodically replace the Interchangeable Component **12** or the Main Body **10** after either has become damaged or has deteriorated from its original condition.

In a preferred embodiment of the invention with application to FIGS. 4-7, the Interchangeable Component **12** (or a portion thereof) is constructed of a relatively more dense material (having a Shore A hardness, for example, of 40) while the Main Body **10** is constructed of a flexible and less dense, cushion-type material (having a Shore A hardness, for example, of 15). This embodiment of the invention affords a means of providing a cushion material over a structural material in the region of longitudinal-arch support. By contrast, the traditional laminar approach provides a structural layer which extends the full length of the Orthotic, as well as a cushion

layer which also extends the full length of the Orthotic. Such a traditional laminar approach for this reason tends to produce the undesirable consequence of greater stack height and weight, and also creates the aforementioned "abrupt discontinuity" problem.

Referring now to FIG. 7, another embodiment of the invention consists of an Interchangeable Component **12** designed to selectively include or not include a protuberance **26** (hereinafter termed the "Metatarsal Pad") in the region just proximal to the area of the metatarsal heads, thereby allowing the option of a device commonly called a "metatarsal pad." Moreover, such Interchangeable Component **12** could be made available with Metatarsal Pads **26** of varying heights.

FIG. 11 shows a representative set of Interchangeable Components **12D**, **12E**, and **12F** designed for use individually by releasable attachment with a complementary orthotic. As used herein, a "set" of Interchangeable Components refers to two or more Interchangeable Components for a particular region of the Orthotic. Sets preferably include 3, 4, 5, 6, 7, 8, 9, or 10, Interchangeable Components, although more such components may also be included. The invention also envisions the combination of two or more sets of Interchangeable Components for a given Orthotic, such as to allow for significant adjustment in two or more regions of the orthotic, e.g., in the arch region and the metatarsal pad region. According to one embodiment, these Interchangeable Components **12D**, **12E**, and **12F** are substantially identical one to another except with

respect to material density. These Interchangeable Components **12D**, **12E**, and **12F** exhibit a range of densities within that range suitable for orthotic function, for example, with Interchangeable Component **12D** having a relatively lower density, Interchangeable Component **12E** having a mid-range density, and Interchangeable Component **12F** having a relatively higher density.

FIG. 12 shows a representative set of Interchangeable Components **12G**, **12H**, and **12I**, each Interchangeable Component being designed for use individually by releasable attachment to a complementary orthotic, with each Interchangeable Component in the set differing in configuration from the others in the set. Accordingly, and as denoted, Interchangeable Component **12G** represents a device for use with a foot having a low-height arch; Interchangeable Component **12H** represents a device for use with a foot having a moderate-height arch; and Interchangeable Component **12I** represents a device for use with a foot having a high-height arch.

FIG. 13 illustrates another representative set of Interchangeable Components **12J**, **12K**, **12L**, **12M**, **12N**, **12O**, **12P**, **12Q**, **12R**, each Interchangeable Component being designed for use individually by releasable attachment to a complementary Orthotic, with each Interchangeable Component in the set differing in the combined characteristics of density and configuration from the others in the set. Accordingly, and as denoted, Interchangeable Component **12J** represents a relatively low-density device for use with a low-arch foot,

Interchangeable Component **12N** represents a medium-density device for use with a medium-height-arch foot, Interchangeable Component **12R** represents a relatively high-density device for use with a high-arch foot, and so on.

Referring to FIGS. 14A-C, an Orthotic Assembly is shown wherein the Main Body **10** has a Vacuity **15** which accepts and retains an Interchangeable Component **12** in such a manner that a portion of the Interchangeable Component **12** on its foot-interface side remains unenclosed by the Main Body **10**, this unenclosed surface being covered by a stretchable material ("Stretchable Cover") **60** which conforms to the Interchangeable Component **12**. Accordingly, FIG. 14A shows an exploded view of the Orthotic Assembly, including the Main Body **10**, the Interchangeable Component **12**, and the Stretchable Cover **60**. Then, FIG. 14B shows the Stretchable Cover **60** attached to the foot-interface surface of the Main Body **10**, with means for insertion of the Interchangeable Component **12** under the Stretchable Cover **60** and into the Vacuity **15** of the Main Body **10**. Finally, FIG. 14C shows the full Orthotic Assembly, including a Main Body **10**, an Interchangeable Component **12** contained therein, and a Stretchable Cover **60** covering and conforming to the assembled Main Body **10** and Interchangeable Component **12**.

Referring to FIGS. 15A-C, a different embodiment of the invention is shown. Here, an Orthotic Assembly is shown wherein a Stretchable Cover **60** is stitched or glued to a Main Body **10** in such a manner as to create a pocket

("Pocket") 62 into which an Interchangeable Component 12 may be inserted. Accordingly, FIG. 15A shows an exploded view of the Main Body 10, the Interchangeable Component 12, and the Stretchable Cover 60. Then, FIG. 15B shows the Stretchable Cover 60 stitched to the Main Body 10 in such a manner as to create the Pocket 62 into which an Interchangeable Component 12 may be inserted. Finally, FIG. 15C shows the full Orthotic Assembly, including a Main Body 10, a Stretchable Cover 60, and an Interchangeable Component 12 residing in the Pocket 62 (not shown) formed between the Main Body 10 and the Stretchable Cover 60. Accordingly, the installed Interchangeable Component 12 is definitively located and adequately retained by the sole and sufficient means of the pocket.

Referring to FIGS. 16A-B, an Orthotic Assembly is shown wherein the Main Body 10 has a Vacuity 15 corresponding in size to a certain size of Interchangeable Component 12 (not shown). The Vacuity 15 can be accessed through an opening (not illustrated), most conveniently located on the underside of the Main Body 10. The Main Body has material gaps or slits ("Expansion Slits" 64) in its foot-interface surface wall in the area corresponding to the Vacuity 15. These Expansion Slits 64 operate to facilitate the accommodation of an oversized Interchangeable Component 12X into the Vacuity 15. Accordingly, the Main Body 10, while having a Vacuity 15 designed to accept a certain size of Interchangeable Component 12 (not shown), can now more readily accept a somewhat larger Interchangeable Component 12X. When the

oversized Interchangeable Component 12X is introduced into the Vacuity 15 of the Main Body 10, the Expansion Slits 64 naturally fan out, as illustrated in FIG. 16B.

Referring to FIGS. 17A-B, a preferred embodiment of the invention consists of an Orthotic Assembly wherein the Main Body 10 has the aforementioned Expansion Slits 64, with the Expansion Slits 64 being covered by a Stretchable Cover 60. Accordingly, FIG. 17A shows the exploded view of such an Orthotic Assembly, and FIG. 17B shows the fully assembled view. Note in FIG. 17B that the Stretchable Cover 60, which is typically glued or stitched to the foot-interface side of the Main Body 10, conceals the Expansion Slits 64 and also provides for a substantially uniform and consistent foot-interface surface. At the same time, the incorporation of the Expansion Slits 64 serves to both accommodate an oversized Interchangeable Component 12X and to prevent wrinkling and/or migration of the Stretchable Cover 60.

Next, referring to FIG. 18, an Orthotic Assembly is shown with a grid-pattern of material voids ("Grid" 70) on the underside of the Main Body 10. This design can afford many advantages, including reduced part weight and greater shock absorption. In the Figure, the material voids have the shape of a hexagonal pyramid. However, any suitable shape, or combination of shapes, or areas with voids of one or more shapes in combination with adjacent areas lacking such voids, can be employed.

In yet another embodiment of the invention, the Main Body 10 can be constructed of a transparent or transluscent material and the Interchangeable Component 12 of an opaque material, with the Interchangeable Component 12 furthermore being of a color corresponding to a color-coded system designating variations in physical properties.

A manufacturing process to produce an Orthotic Assembly corresponding to a preferred embodiment of the invention is now described in greater detail. (While the application discussed herein assumes a gravity-pour molding process with two mold halves, the invention would apply to many other processes including, but not limited to, compression molding, vacuum-form molding, injection molding, and reaction-injection molding). Referring to FIG. 8, an insert molding process is employed wherein a durable mold insert 28 (hereinafter termed "the Slug") having the shape of the Interchangeable Component (not illustrated here) is placed in a precise location within the cavity formed by two mold halves. The Slug 28 has a thin rail 28A (hereinafter termed "the Rail") which in turn is attached to locating pins 28B (hereinafter termed "Locating Pins"). In the lower mold half (hereinafter termed "the Mold Cavity") 31 there is a slot (hereinafter termed "the Slot") 36 corresponding to the Rail 28A , but such Slot 36 having a lesser vertical dimension than that of the Rail 28A. In the bottom of the Slot 36 are locating pin holes 38 (hereinafter termed "Locating Pin Holes") to receive the aforementioned Locating Pins 28B. After the Slug 28 is positioned in the Mold Cavity 31

(with the Rail 28A seated in the Slot 36 and the Locating Pins 28B seated in the Locating Pin Holes 38), molding material is introduced into the mold, and the material is allowed to take the form of the desired part.

Continuing with the process, after an appropriate delay, the mold is opened. Referring now to FIG. 9, the molding process has produced a molded product 40 which is removed from the mold, and such product should be understood to consist of the Main Body 10 and the Slug 28 which is embedded within the Main Body 10, with a portion of the Rail 28A (and locating pins 28B) protruding from the underside of the Main Body 10. The post-molding removal of the Slug 28 (with Rail 28A and locating pins 28B) leaves the Main Body 10 with a precisely located vacuity having the mating contour and dimensions of the Slug 28 which was removed. This vacuity, of course, would be the Conforming Enclosure (not illustrated here) which will readily accept the Interchangeable Component (not illustrated here).

A novel tooling design, hereinafter termed the "Modular Design," is now discussed. The Modular Design may be utilized in the manufacture of Orthotics in order to reduce both tooling cost and set-up time. (While the application discussed herein assumes a molding process with two mold halves, the invention would apply to many other processes including, but not limited to, vacuum-form molding). Referring now to FIG. 10, mold bases are utilized on both mold halves and are referred to individually as the "Mold Core Base" 42 and the "Mold

Cavity Base" 44. According to the Modular Design, the entire part-defining portions of the mold cavity and the mold core are each set up as interchangeable mold insert members, hereinafter respectively termed the "Core Standard Size Insert" 46 and the "Cavity Standard Size Insert" 48, with such inserts defining the orthotic form and dimensions, such dimensions including length and width corresponding to a particular conventional foot size (e.g., 11-D). The Core Standard Size Insert 46 should be understood to define the foot-interfacing surface of the orthotic, while the Cavity Standard Size Insert 48 should be understood to define the shoe-interface surface of the orthotic. In the preferred embodiment of the invention, the Core Standard Size Insert 46 is designed to contain yet another interchangeable mold insert member, hereinafter termed "the Contour Insert" 50. The Contour Insert 50 provides the longitudinal-arch contour, from roughly the heel to roughly the ball of the foot. Employing the Modular Design of tooling, a molding facility could mold many Orthotics corresponding to a particular generic foot size (e.g., 11-D) - each with custom longitudinal-arch contours - with only a quick substitution of Contour Inserts 50 (and possibly Slugs 28, if producing an Orthotic Assembly in accordance with the invention). The facility could then change the Cavity Standard Size Insert 48 and Core Standard Size Insert 46 to another conventional size (e.g., 9-B) and proceed in the same manner to mold a batch of Orthotics of this size - each with custom longitudinal-arch contours - again having only to change the Contour Inserts 50 (and

possibly Slugs **28**, if producing an Orthotic Assembly in accordance with the invention) between moldings.

Notwithstanding specific descriptions and illustrations made with reference to preferred embodiments, the inventions disclosed herein are not to be limited to such constructions. Moreover, various changes and modifications made within the spirit of the inventions are understood to be covered by the appended claims:

I claim:

1. An orthotic assembly comprising

a main body and an interchangeable component,

said main body having an accessible vacuity for releasably receiving said interchangeable component,

said interchangeable component having an orthotic function,

said interchangeable component having a shape configured for said orthotic function and a substantially homogeneous and uninterrupted surface,

said vacuity in said main body substantially mating to said configured shape of said interchangeable component itself,

said interchangeable component and said vacuity thereby constituting a matching set with substantially mating configuration, said matching set being located appropriately for said orthotic function, and

said mating configuration being the sole and only means of locating and retaining said interchangeable component in said main body.

2. An orthotic assembly of claim 1 wherein said vacuity is formed by a flexible and stretchable material.

3. An orthotic assembly comprising

a main body and an interchangeable component,

said main body having an accessible vacuity for releasably receiving said interchangeable component, and

said vacuity being formed within the main body by a flexible and stretchable material,

said interchangeable component having an orthotic function.

4. An orthotic assembly of claim 3 wherein

said vacuity in said main body substantially mates to said configured shape of said interchangeable component, thereby forming a matching set,

said matching set being located appropriately for said orthotic function, and

said mating configuration being the sole and only means of locating and retaining said interchangeable component in said main body.

5. An orthotic assembly comprising

a main body and an interchangeable component,

said main body having an accessible vacuity for releasably receiving said interchangeable component,

said interchangeable component having an orthotic function and a substantially homogeneous and uninterrupted surface,

said interchangeable component having a shape configured for said orthotic function,

said vacuity being formed within the main body by a flexible and stretchable material,

said vacuity in said main body substantially mating to said shape of said interchangeable component thereby forming a matching set, said matching set being located appropriately for said orthotic function, and

said mating configuration being the sole and only means of locating and retaining said interchangeable component in said main body.

6. An orthotic assembly of claim 5 wherein said interchangeable component is substantially encapsulated when installed in said main body.

7. An orthotic assembly of claim 5 wherein said interchangeable component is installed in that area of said main body corresponding to the longitudinal arch of a foot.

8. An orthotic assembly of claim 5 wherein said interchangeable component is comprised of an opaque material and said main body is comprised of a transparent material.

9. An orthotic assembly of claim 5 wherein said interchangeable component incorporates a protuberance in the region just proximal to the area of the metatarsal heads.

10. An orthotic assembly of claim 5 wherein said main body material is of a different density from that of said interchangeable component.

11. An orthotic assembly comprising

a main body and an interchangeable component,

said main body having an accessible vacuity for releasably receiving said interchangeable component,

said interchangeable component having an orthotic function,

said interchangeable component having a shape configured for said orthotic function and a substantially homogeneous and uninterrupted surface,

said vacuity being formed within the main body by a flexible and stretchable material,

said vacuity in said main body substantially mating to said shape of said interchangeable component, thereby forming a matching set,

said matching set being located appropriately for said orthotic function,

said interchangeable component being substantially encapsulated when installed in said main body, and

said mating configuration being the sole and only means of locating and retaining said interchangeable component in said main body.

12. An orthotic assembly comprising

a main body and an interchangeable component,

said main body having an accessible vacuity for releasably receiving said interchangeable component,

said interchangeable component having an orthotic function,

said interchangeable component when so received in said vacuity being located in that area of said main body corresponding to the longitudinal arch of a foot,

said interchangeable component having a shape configured for said orthotic function and a substantially homogeneous and uninterrupted surface,

said vacuity being formed within the main body by a flexible and stretchable material,

said vacuity in said main body substantially mating to said configured shape of said interchangeable component thereby forming a matching set,

said matching set being located appropriately for said orthotic function,

said interchangeable component being substantially encapsulated when installed in said main body, and

said mating configuration being the sole and only means of locating and retaining said interchangeable component in said main body.

13. An orthotic assembly according to claim 1 having more than one said matching set.

14. A mold for making an orthotic, comprising two mold halves,

a first mold insert member being contained within one of said mold halves,

a second mold insert member being contained within the other of said mold halves,

said first and second mold insert members cooperatively defining an orthotic having dimensions corresponding to conventional length and width foot sizes.

15. A mold for making an orthotic, comprising,

at least one mold surface defining the foot-interfacing form of said orthotic,

said mold surface including a mold insert member defining that portion of said foot-interfacing form of said orthotic corresponding to that area of the foot extending from the heel to the ball.

16. A mold for making an orthotic, comprising,

two mold halves,

a first mold insert member being contained within one of said mold halves, said first mold insert member defining the shoe-interface form of the orthotic,

a second mold insert member being contained within the other of said mold halves, said second mold insert member defining the foot-interface form of the orthotic,

said first and second mold insert members cooperatively defining an orthotic having dimensions corresponding to conventional length and width foot sizes,

a third mold insert member disposed in said second mold insert member,

said third mold insert member defining that portion of the foot-interfacing form of said orthotic corresponding to that area of the foot extending from the heel to the ball.

17. A mold for making an orthotic, said orthotic including a main body and an interchangeable component, said mold comprising,

at least one mold surface defining a foot-interfacing form of said orthotic,

a mold insert member disposed proximal to said mold surface,

said mold insert member corresponding to a vacuity in said orthotic whereby said vacuity affords the subsequent releasable receipt of said interchangeable component within said main body.

18. A mold of claim 14 said mold to produce an orthotic having a main body and an interchangeable component, said mold to further comprise

a mold insert member corresponding to a vacuity in said orthotic whereby said vacuity affords the subsequent releasable receipt of said interchangeable component within said main body.

19. A set of interchangeable components for use individually by releasable attachment with a complementary orthotic,

said interchangeable components being substantially identical one to another except with respect to material density,

said interchangeable components having a range of densities corresponding to that range suitable for orthotic function.

20. A set of interchangeable components of claim 19, said set being designed for support of the longitudinal arch of a human foot.

21. A set of interchangeable components for use individually by releasable attachment with a complementary orthotic,

said set being designed for support of the longitudinal arch of a human foot,

said interchangeable components being substantially identical one to another except with respect to material density,

said interchangeable components having a range of densities corresponding to that range suitable for their orthotic function.

22. A set of interchangeable components of claim 20 wherein said interchangeable components differ in configuration,

said differing configurations corresponding to a subset of differing shapes of a longitudinal arch found in the human foot.

23. A set of interchangeable components for use individually by releasable attachment with a complementary orthotic,

said interchangeable components being designed for support of a longitudinal arch of a human foot,

said interchangeable components being substantially identical one to another except with respect to configuration,

said differing configurations corresponding to a subset of differing shapes of the longitudinal arch found in the human foot.

24. A set of interchangeable components for use individually by releasable attachment with a complementary orthotic,

said set being designed for support of a longitudinal arch of a human foot,

said interchangeable components being substantially identical one to another except with respect to material density and except with respect to the configuration on

that portion of said interchangeable components corresponding to said longitudinal arch,

said interchangeable components having a range of densities corresponding to that range suitable for their orthotic function,

said interchangeable components having a range of configurations corresponding

to a subset of the differing shapes of longitudinal arch found in the human foot.

25. An orthotic assembly of claim 1 wherein said main body partially encloses the interchangeable component,

said partial enclosure revealing an exposed surface of the interchangeable component,

said exposed surface being on that side of said interchangeable component proximate to the foot when said interchangeable component is installed in said body,

said exposed surface being covered by a stretchable material, and

said stretchable material being stretched into conformance with said exposed surface.

26. An orthotic assembly comprising

a main body, an interchangeable component, and a stretchable cover,

said main body and said stretchable cover being selectively attached so as to create a pocket having entry means for releasably receiving said interchangeable component.

27. An orthotic assembly of claim 26 wherein said interchangeable component is designed for support of the longitudinal arch of a human foot.

28. An orthotic assembly comprising

a main body, an interchangeable component, and a stretchable cover,

said main body and said stretchable cover being selectively attached so as to create a pocket having entry means for releasably receiving said interchangeable component,

said interchangeable component is designed for support of the longitudinal arch of a human foot.

29. An orthotic assembly of claim 1 wherein said main body contains expansion slits in the main body,

said expansion slits being located in the foot-proximate wall defining said vacuity.

30. An orthotic assembly of claim 29 wherein said expansion slits are covered on the foot-interface side by a stretchable material,

said stretchable material being applied to conform with said main body in the region of said expansion slits.

31. An orthotic assembly of claim 1 wherein said main body contains a grid pattern of material voids on the side of said main body opposite to the foot-interface side.

32. An article of footwear comprising an Orthotic assembly according to claim 1 functionally associated therewith.

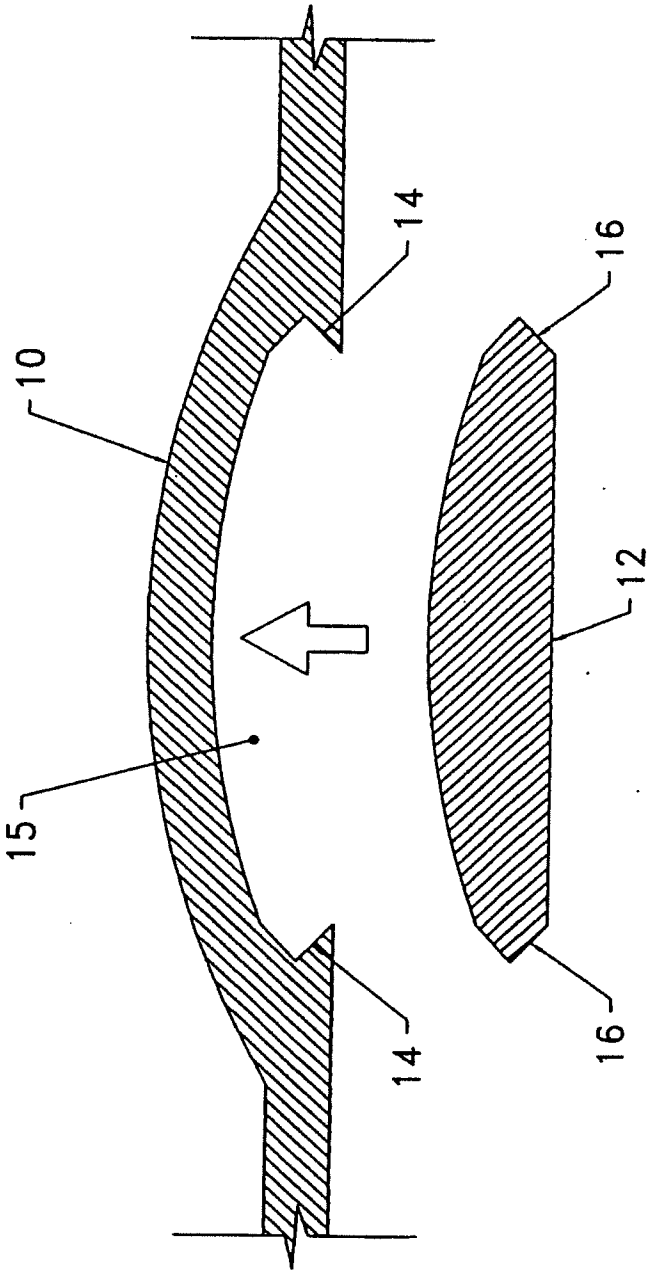


Fig. 1

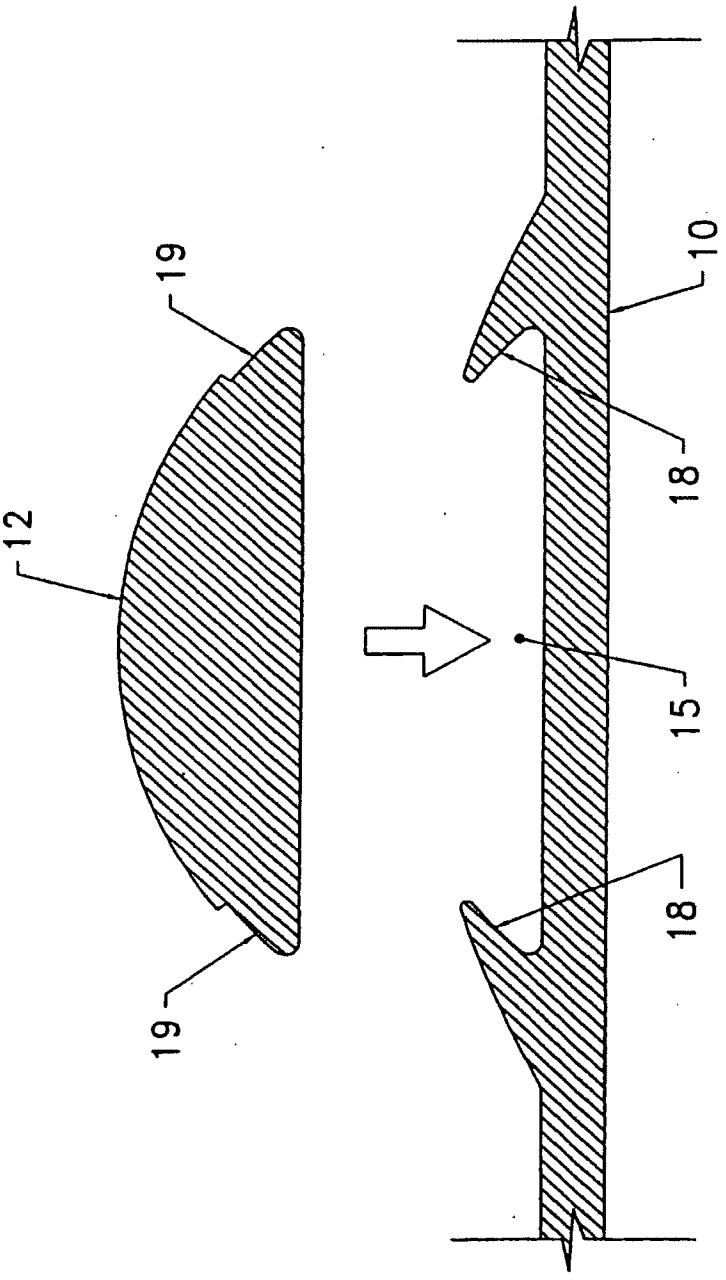
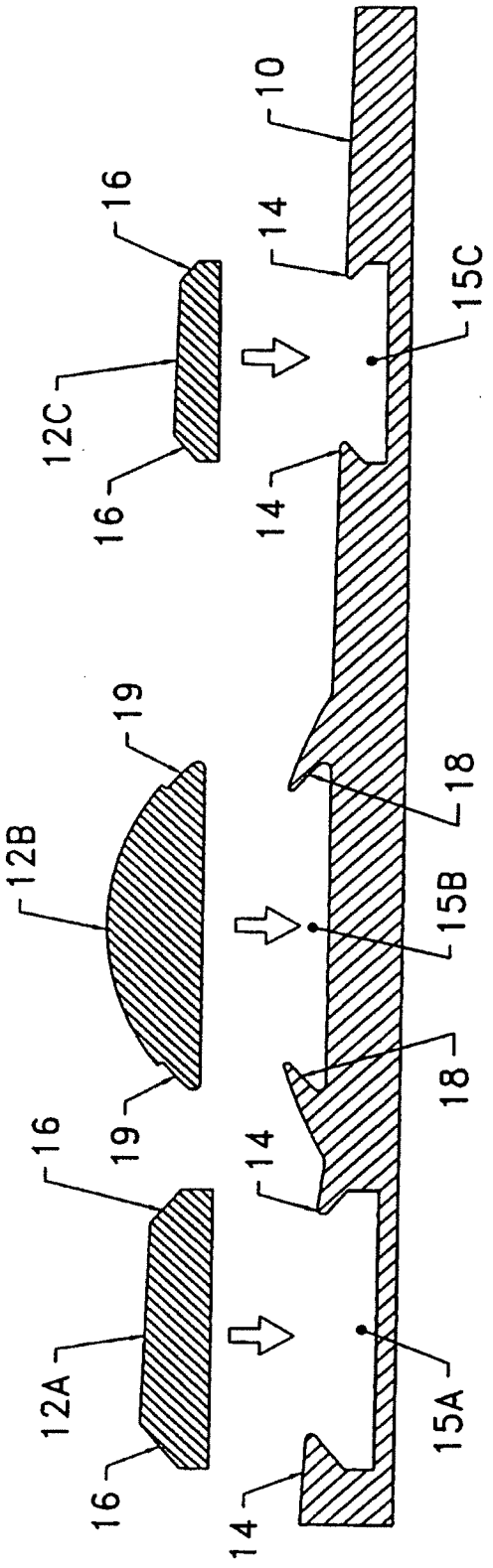


Fig. 2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12C
16
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ARCH
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15A
16
14
HEEL

Fig. 3

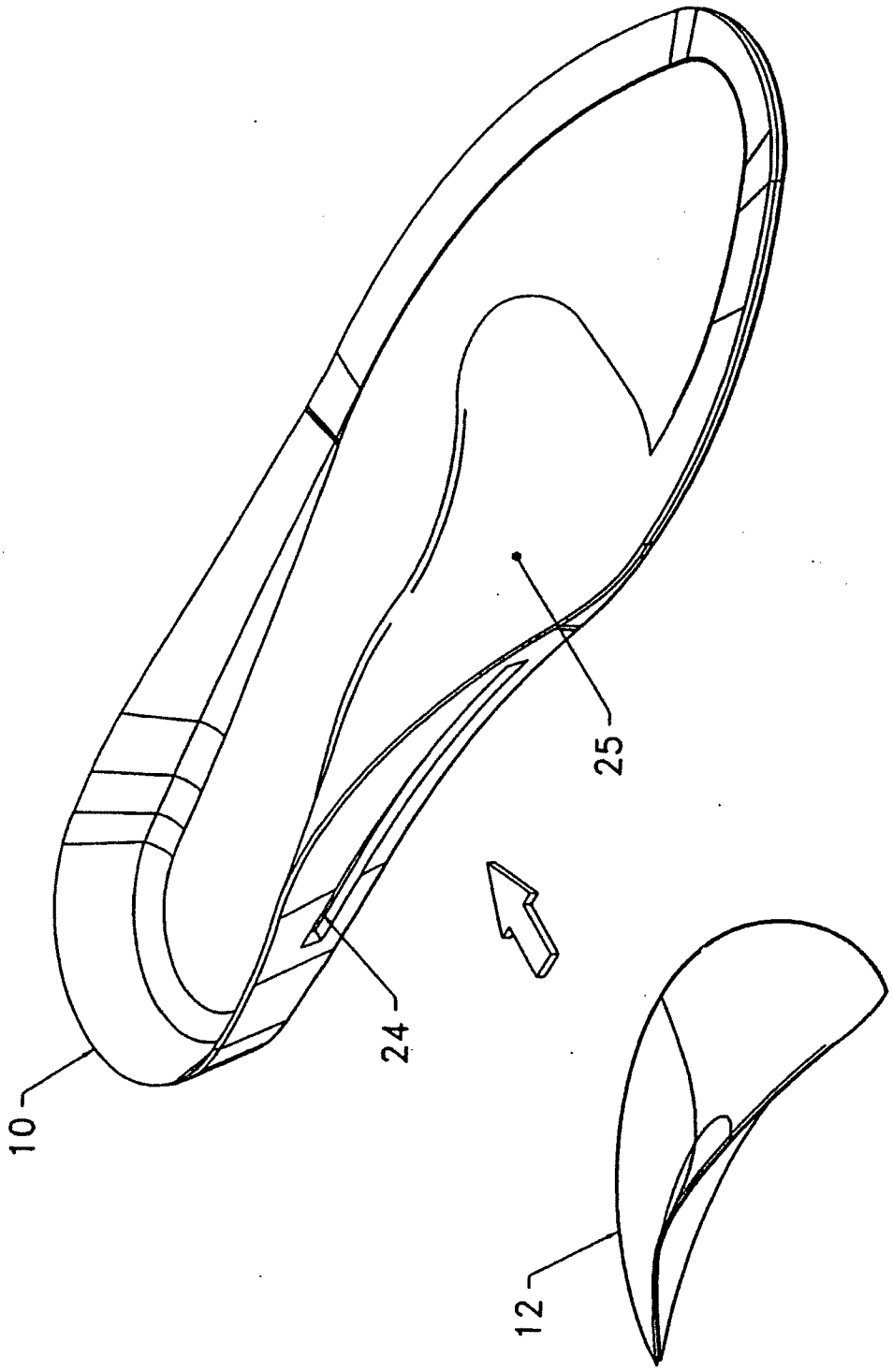


Fig. 4

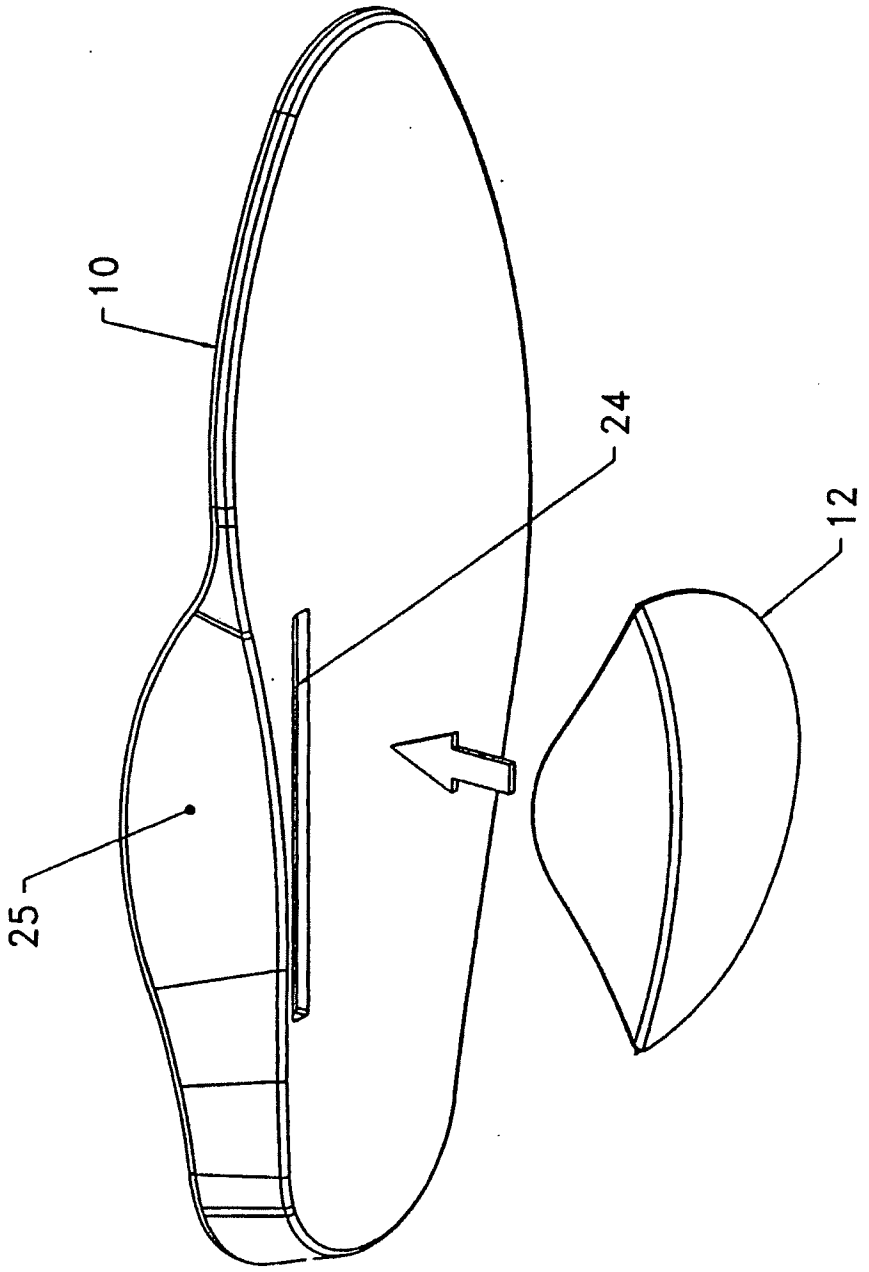


Fig. 5

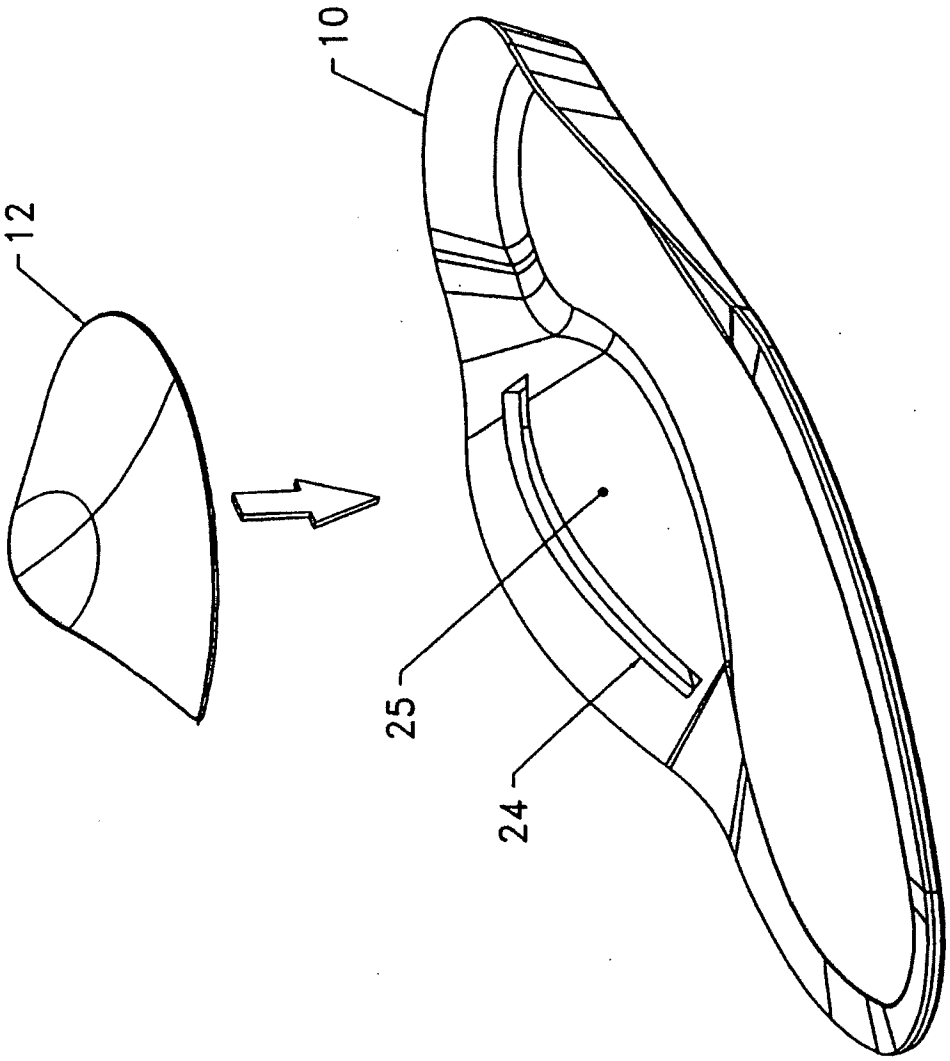


Fig. 6

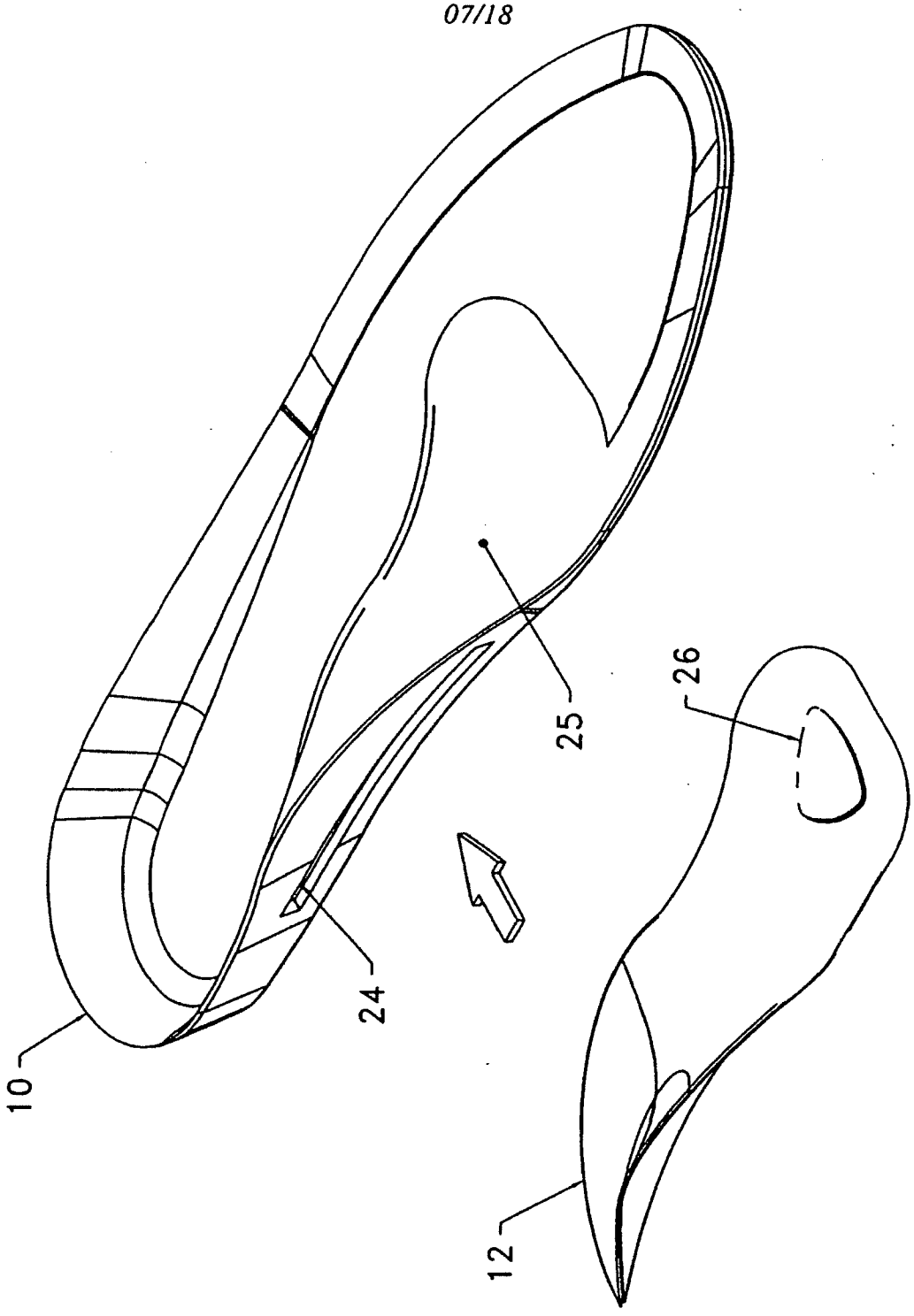


Fig. 7

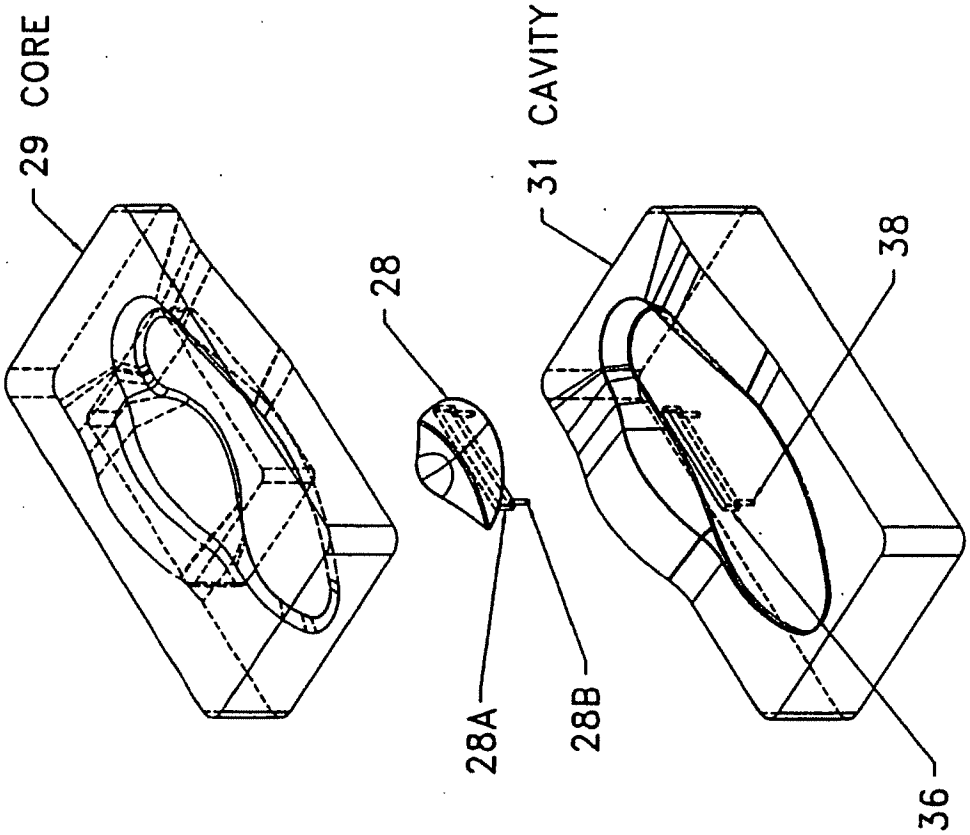


Fig. 8

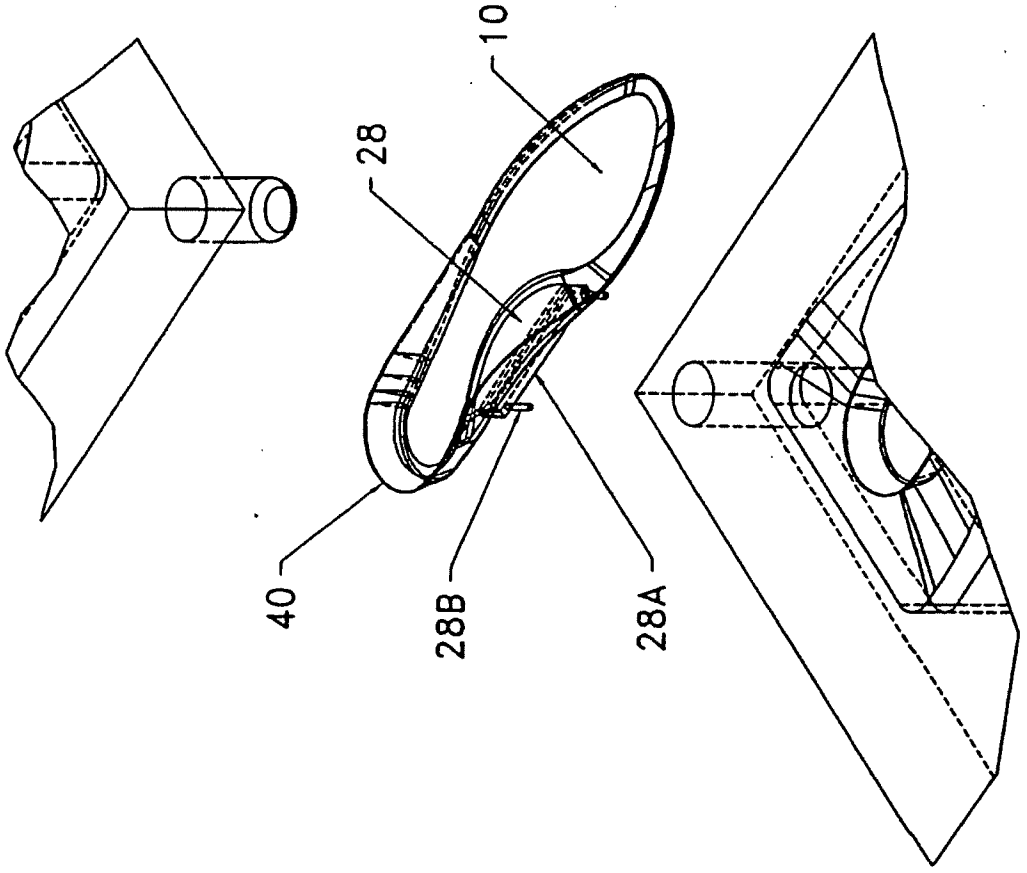


Fig. 9

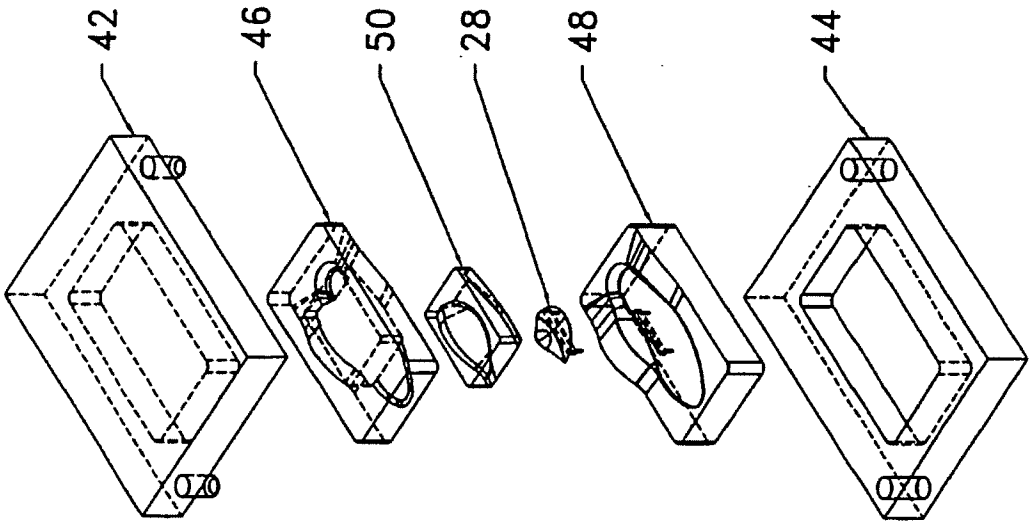


Fig. 10

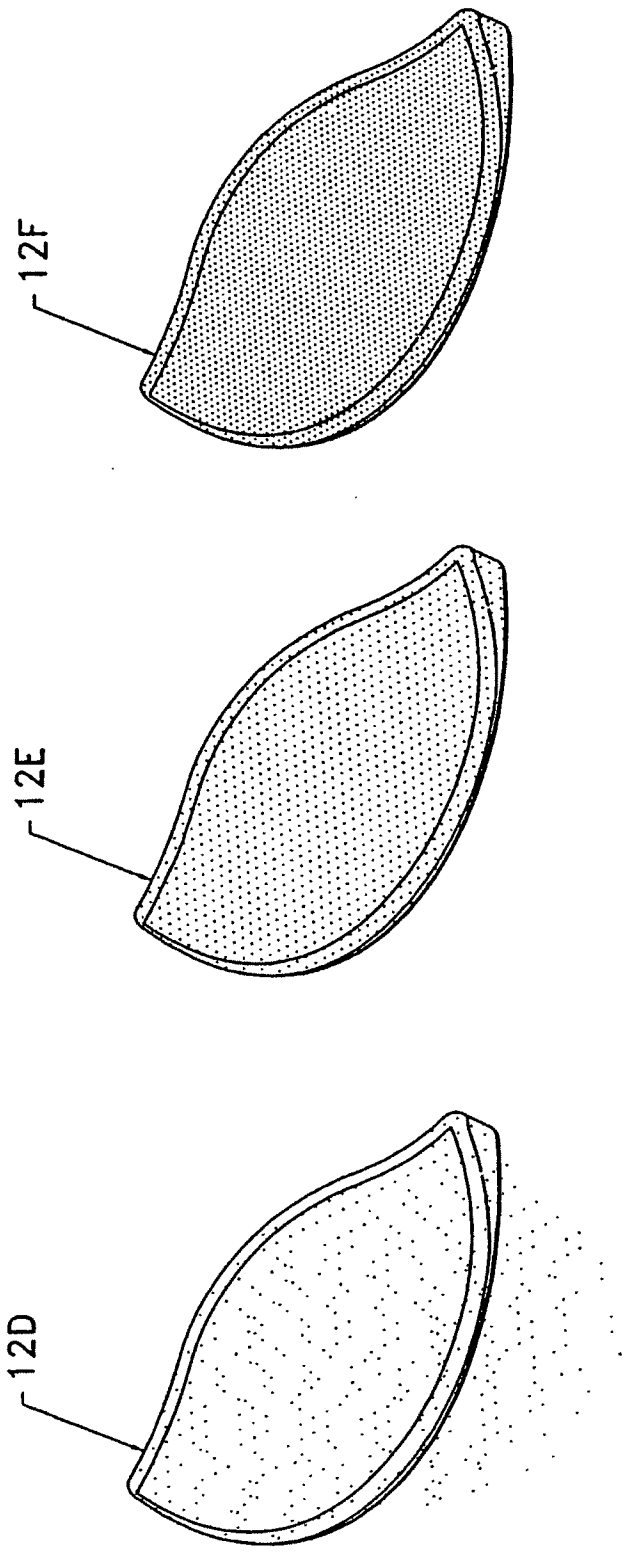


Fig. 11

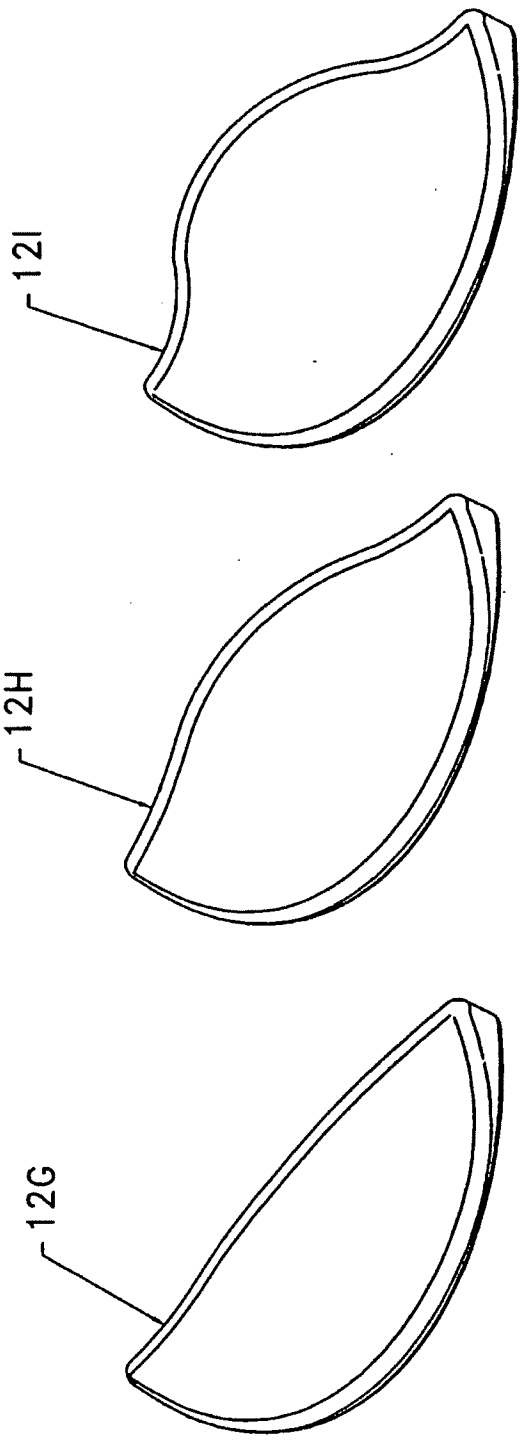
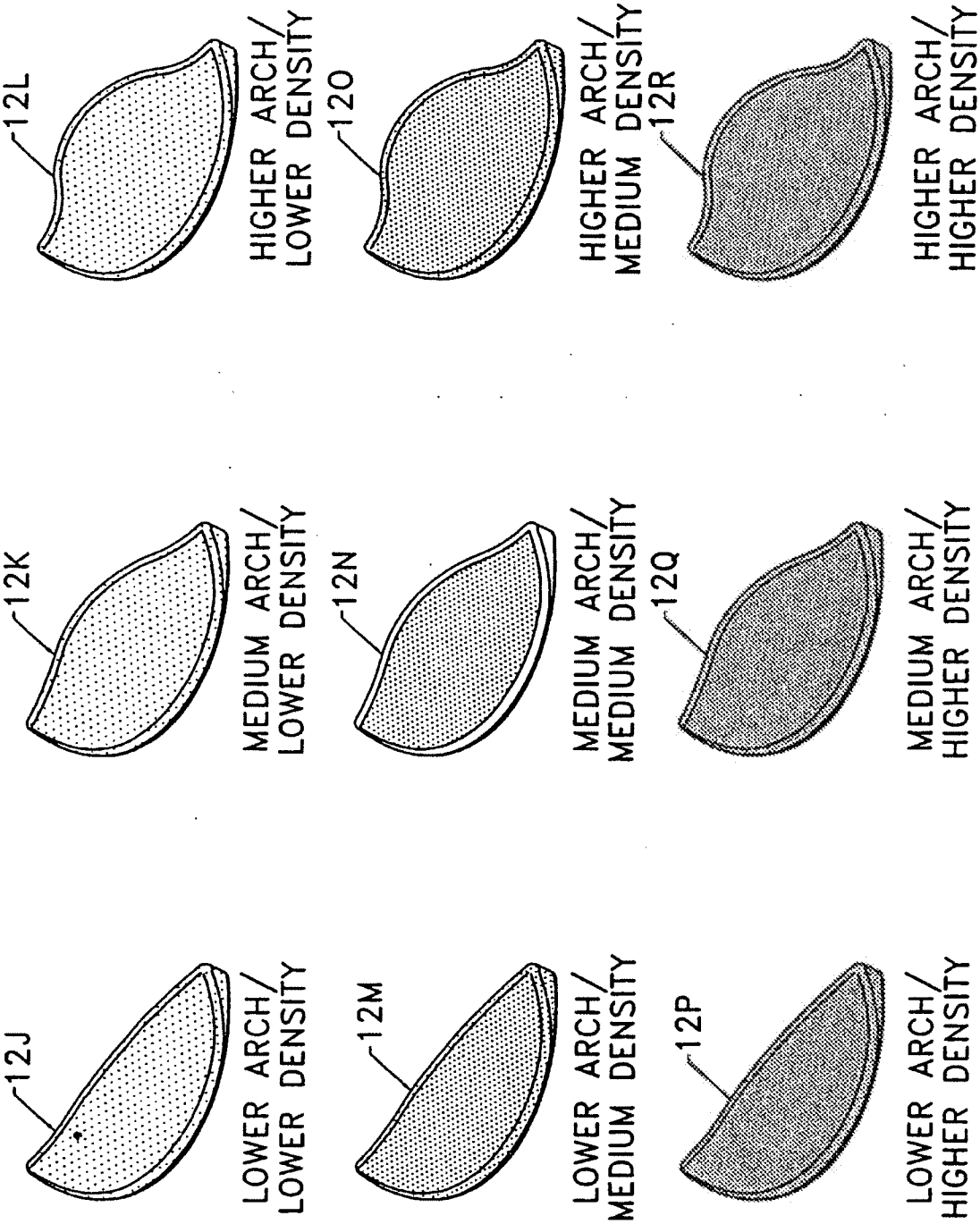


Fig. 12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LOWER DENSITY
12K
MEDIUM ARCH/
LOWER DENSITY
12L
HIGHER ARCH/
LOWER DENSITY
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12N
MEDIUM ARCH/
MEDIUM DENSITY
12O
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MEDIUM DENSITY
12P
LOWER ARCH/
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12Q
MEDIUM ARCH/
HIGHER DENSITY
12R
HIGHER ARCH/
HIGHER DENSITY

Fig. 13

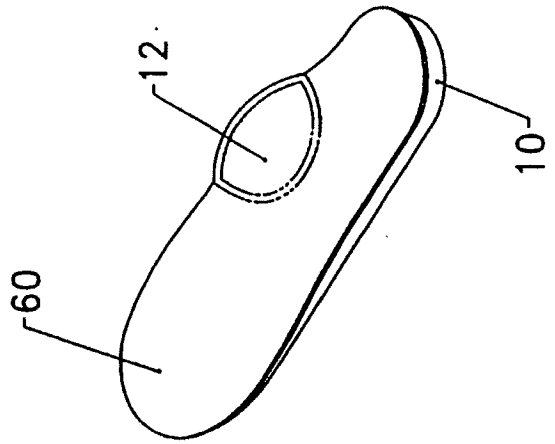

Fig. 14C

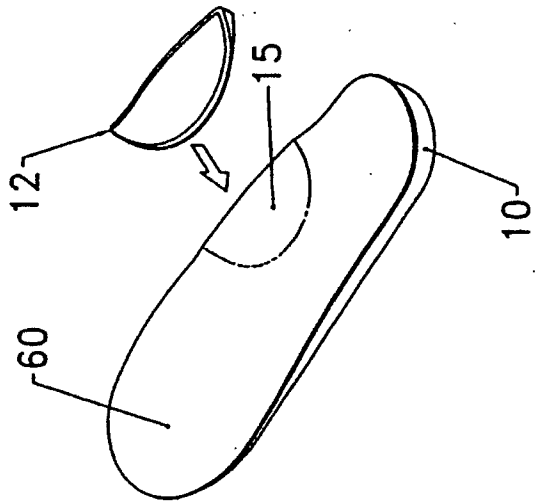

Fig. 14B

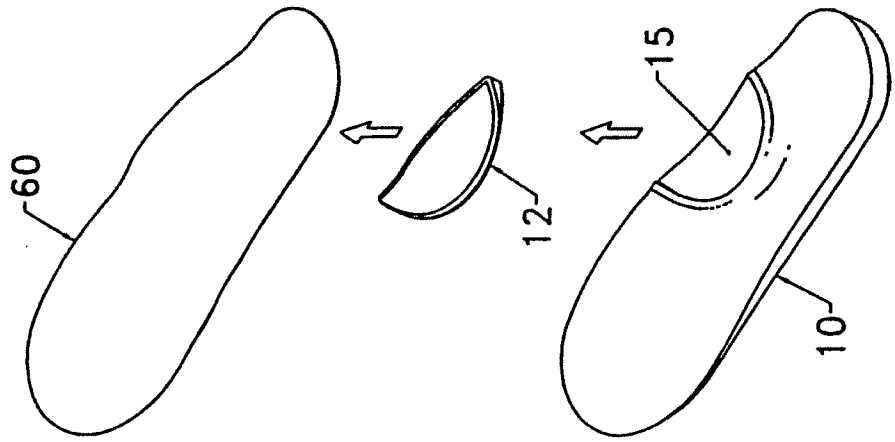

Fig. 14A

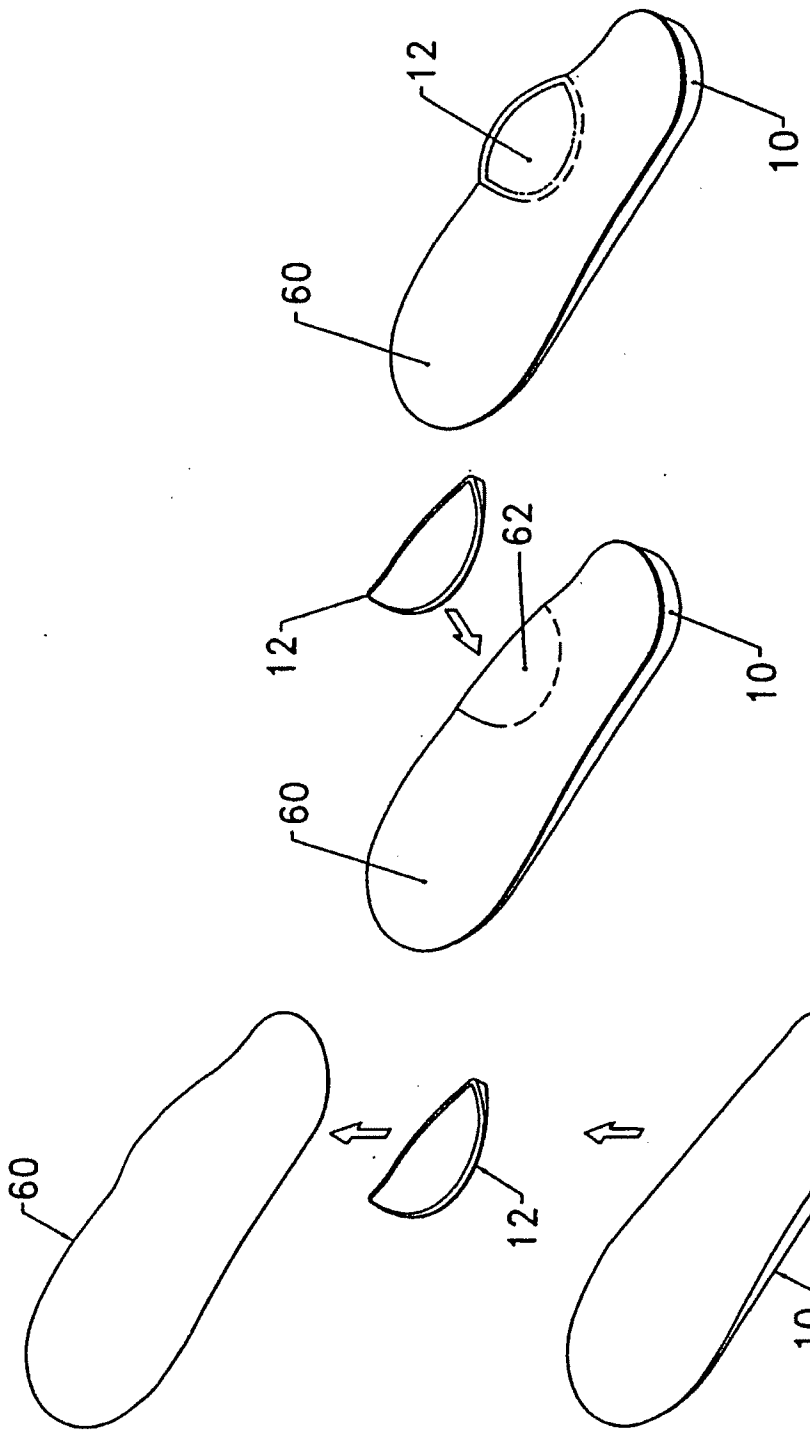

Fig. 15C

Fig. 15B

Fig. 15A

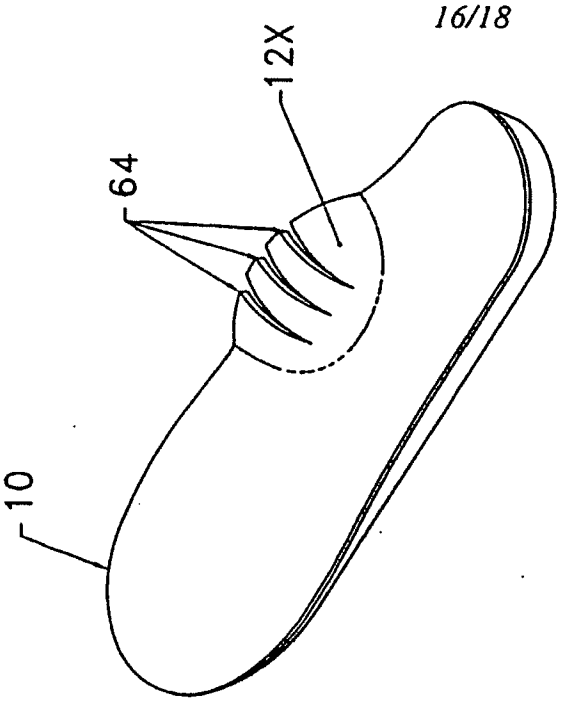

Fig. 16B

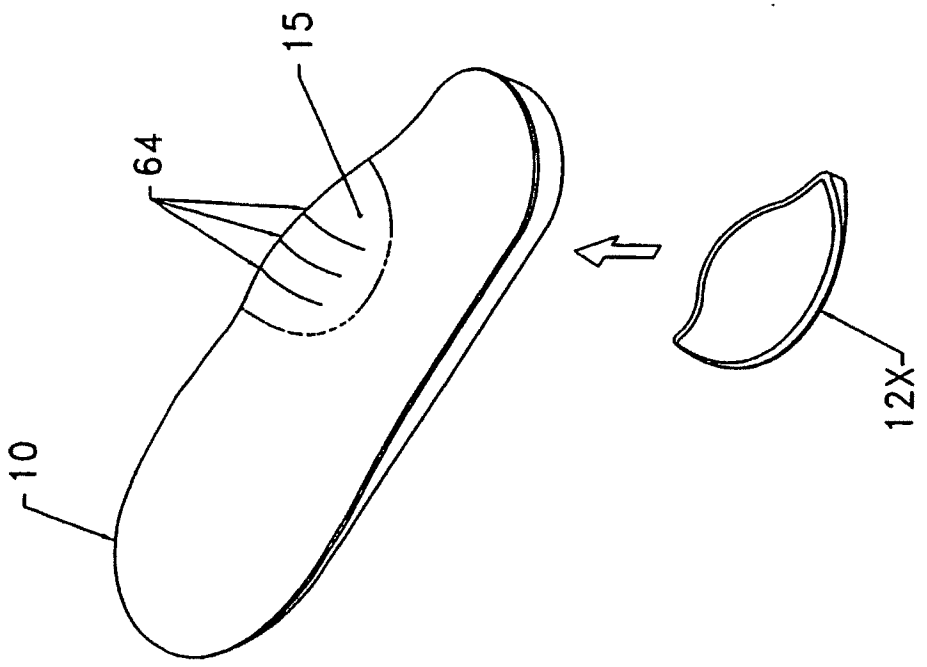

Fig. 16A

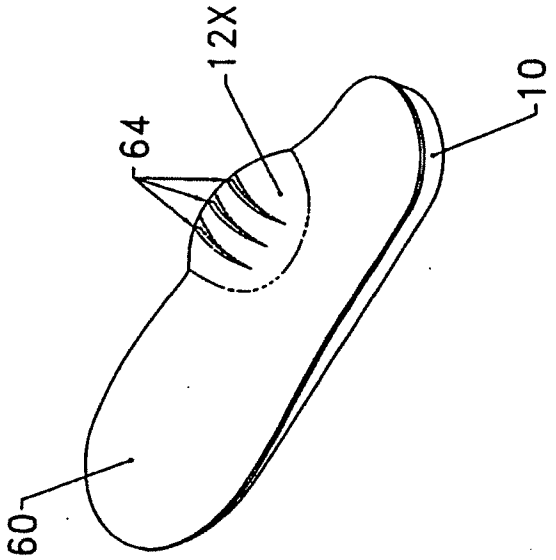

Fig. 17B

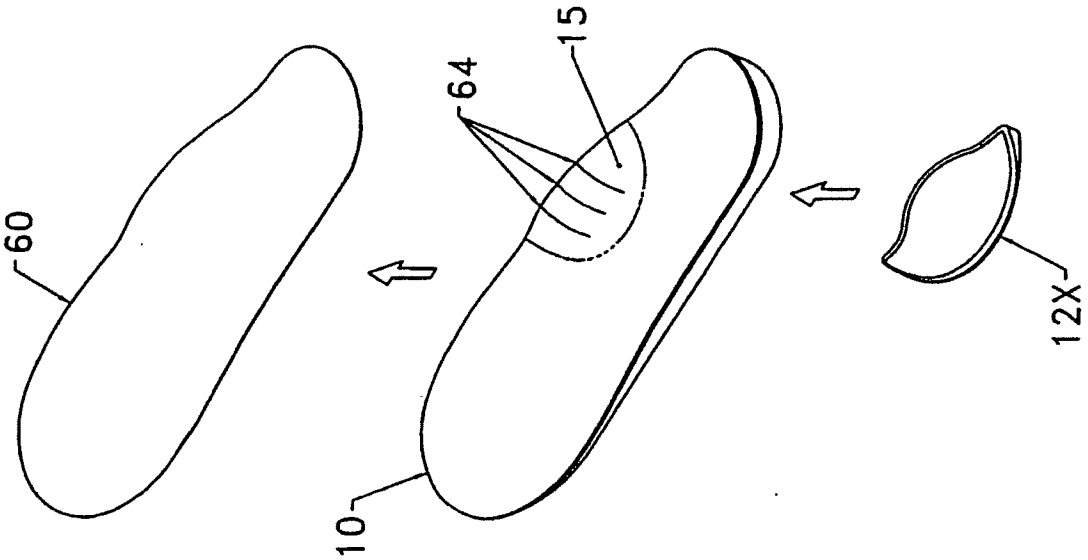

Fig. 17A

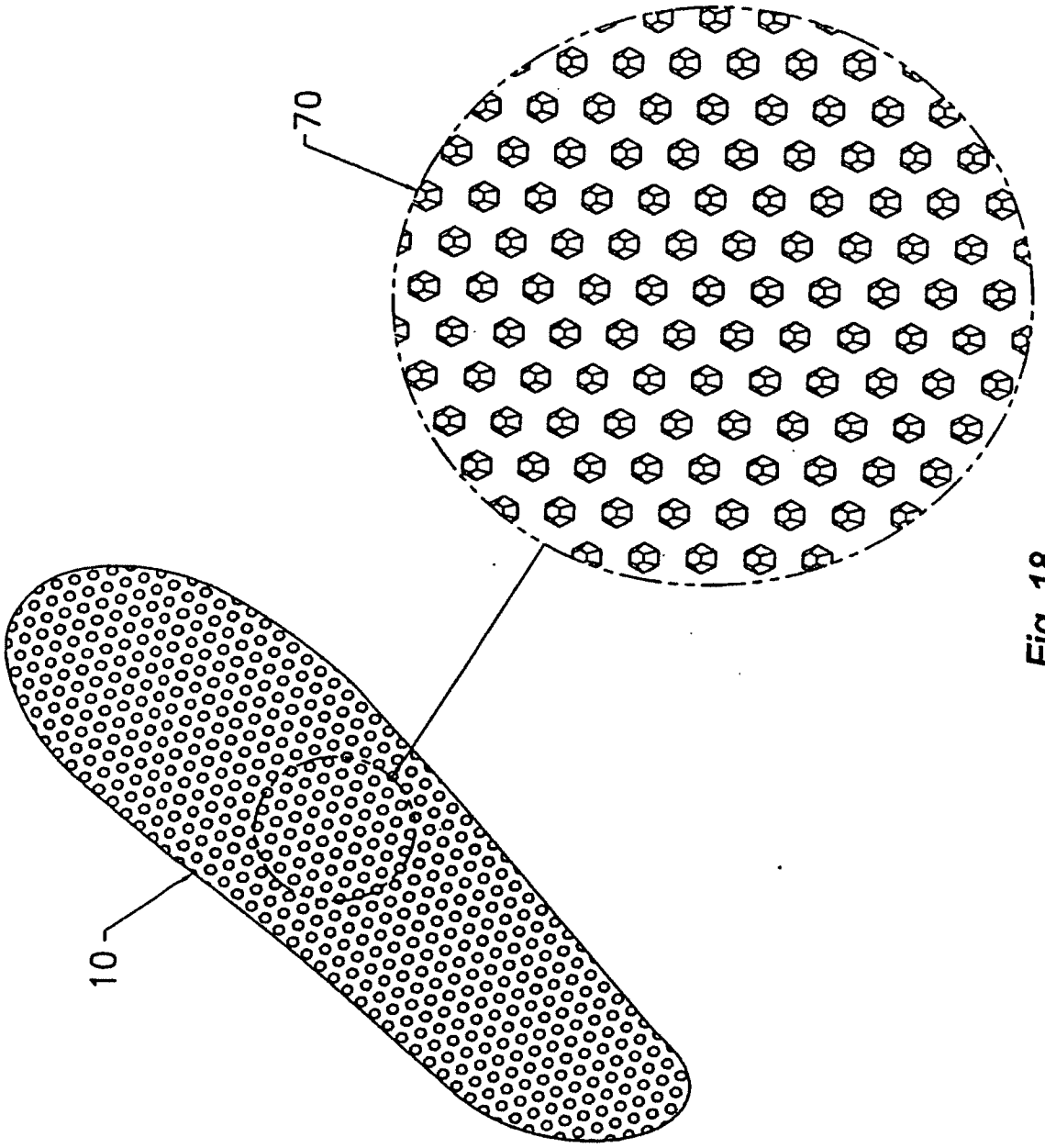

Fig. 18

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/03080

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A43B7/14 A43B7/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A43B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 138 774 A (J. SARKOZI) 18 August 1992 see the whole document ---	1-13,32 19-30
A	WO 93 13685 A (BAUERFEIND) 22 July 1993 see the whole document ---	1-13
A	US 3 339 555 A (R. ROTKO) 5 September 1967 see the whole document ---	1-13
A	US 2 736 971 A (C. ELSEY) 6 March 1956 see the whole document ---	1-13
A	EP 0 316 289 A (L. GERI) 17 May 1989 see the whole document -----	1-13

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 June 1998	24.09.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	DECLERCK, J

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national application No.

PCT/US 98/ 03080

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims: 1-13,19-32
2. Claims: 14-18

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1.Claims: 1-13,19-32

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

formation on patent family members

Int ~~ional Application No
PCT/US 98/03080

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5138774 A	18-08-1992	CA 2075265 A,C	05-02-1994
WO 9313685 A	22-07-1993	DE 4200362 A	15-07-1993
		EP 0621755 A	02-11-1994
		JP 7505537 T	22-06-1995
		US 5438768 A	08-08-1995
US 3339555 A	05-09-1967	NONE	
US 2736971 A	06-03-1956	NONE	
EP 0316289 A	17-05-1989	AU 2479988 A	11-05-1989
		CA 1308554 A	13-10-1992
		DE 3884755 D	11-11-1993
		DE 3884755 T	27-01-1994
		ES 2045186 T	16-01-1994
		US 5005575 A	09-04-1991